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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,566	11/11/2003	Hans-Jurgen Wachter	100727-61 / Kreisler 412	4253
27384	7590	09/15/2010		
Briscoe, Kurt G. Norris McLaughlin & Marcus, PA 875 Third Avenue, 8th Floor New York, NY 10022			EXAMINER KESSLER, CHRISTOPHER S	
			ART UNIT	PAPER NUMBER
			1793	
			MAIL DATE	DELIVERY MODE
			09/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/705,566	Applicant(s) WACHTER ET AL.	
	Examiner CHRISTOPHER KESSLER	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 September 2010 has been entered.

Status of Claims

2. Responsive to the amendment filed 2 September 2010, claims 13 and 15 are amended and new claims 20 and 21 are added. Claims 16-19 are withdrawn as being directed to a non-elected invention. Claims 1-15 and 20-21 are currently under examination.

Status of Previous Rejections

3. Responsive to the amendment filed 2 September 2010, new grounds of rejection are presented corresponding to new claim 21.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5-10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 6,767,360 issued to Alt et al. (hereinafter "Alt").

Regarding claim 1, Alt discloses the invention substantially as claimed. Alt discloses a niobium alloy for a medical device comprising preferably less than 1% zirconium, remainder niobium (see col. 4, lines 25-50). The compositional range significantly overlaps the range claimed by applicant, thus establishing a prima facie case of obviousness for that range (see MPEP §2144.05). It would have been obvious to one of ordinary skill in the art to have selected the claimed compositional range because Alt teaches the same utility over the entire range.

Regarding claim 2, Alt is applied to the claim as stated above.

Regarding claim 3, Alt is applied to the claim as stated above.

Regarding claim 5, Alt discloses wherein the medical device is a stent (see abstract, for example), meeting the limitation of being intra-cavernous.

Regarding claim 6, Alt discloses wherein the medical device is a stent (see abstract, for example), meeting the limitation of being an intravascular implant

Regarding claim 7, Alt discloses wherein the medical device is a stent (see abstract, for example).

Regarding claim 8, Alt teaches that the alloy is used to make a stent (see SUMMARY OF THE INVENTION, cols. 4-9, or fig. 1, for example). The alloy composition of Alt is cited in the rejections above.

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Regarding claim 9, Alt teaches that the alloy is used to make a stent (see SUMMARY OF THE INVENTION, cols. 4-9, or fig. 1, for example). The alloy composition of Alt is cited in the rejections above.

Regarding claim 10, Alt discloses wherein an oxidation process passivates the stent (see col. 8, lines 16-44, for example).

Regarding claim 12, Alt discloses wherein the stent is sintered (see col. 6, lines 31-47, for example).

Regarding claim 13, Alt discloses wherein the stent is coated with a layer of niobium oxide (see col. 8, lines 16-44, for example).

6. Claims 11, 14, 15, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claims 1-3 above, and further in view of U.S. Patent 6,387,121 issued to Alt (hereinafter "Alt '121").

Regarding claim 11, Alt does not disclose wherein the surface of the metal alloy is coated by iridium oxide by vapor deposition.

Alt '121 discloses a coated stent for vascular and endoluminal applications. Alt '121 clearly teaches that a layer of iridium oxide is coated onto the stent (see SUMMARY OF THE INVENTION, for example). It would have been obvious to one of ordinary skill in the art at the time of invention to alter the invention of Alt by coating the stent with iridium oxide, as taught by Alt '121 (cited above), in order to provide a means to deliver drugs to preclude thrombosis, as taught by Alt '121 (see SUMMARY OF THE INVENTION, for example).

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Regarding claim 14, Alt does not disclose wherein the surface of the metal alloy is coated with stem cells and or a bioactive substance.

Alt '121 teaches that a stent is coated with iridium oxide to act as a carrier for beneficial drugs (see SUMMARY OF THE INVENTION, for example). It would have been obvious to one of ordinary skill in the art at time of invention to alter the invention of Alt by coating the stent with a beneficial drug, as taught by Alt '121 (cited above), in order to preclude occlusion from restenosis or thrombosis (see SUMMARY OF THE INVENTION).

Regarding claim 15, Alt '121 teaches that the beneficial drug may include a drug to preclude occlusion from restenosis or thrombosis (see SUMMARY OF THE INVENTION, for example), meeting the limitations of the claim.

Regarding claim 20, Alt '121 teaches that a viral vector may be included in the surface of the stent (see col. 9), meeting the limitation of nucleic acids.

Regarding claim 21, Alt '121 teaches that the viral vector may block growth factors to prevent restenosis (see col. 9), meeting the limitation of morphogenic proteins.

7. Claims 1, 2, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,845,259 issued to Pacetti et al. (hereinafter "Pacetti"), in view of Alt.

Regarding claim 1, Pacetti teaches that a guide wire is made from a niobium alloy in order to allow the guide wire to appear in MRI (see SUMMARY OF THE

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INVENTION, for example). Pacetti does not disclose wherein the alloy is a niobium/zirconium alloy.

Alt discloses a niobium alloy for a medical device comprising preferably less than 1% zirconium, remainder niobium (see col. 4, lines 25-50). The compositional range significantly overlaps the ranges claimed by applicant, thus establishing a prima facie case of obviousness for that range (see MPEP §2144.05). It would have been obvious to one of ordinary skill in the art to have selected the claimed compositional range because Alt teaches the same utility over the entire range. Alt further teaches a balloon angioplasty procedure, and it is well known in the art to install a stent *in vivo* through use of a guide wire during a balloon angioplasty (see col. 1, lines 32-51, for example).

It would have been obvious to one of ordinary skill in the art at time of invention to alter the invention of Pacetti by using the specific niobium alloy disclosed in Alt (cited above), in order to make a guide wire that would not distort the magnetic resonance field, as taught by Alt (see col. 2, lines 30-50).

Regarding claim 2, Pacetti and Alt are applied to the claim as stated above.

Regarding claim 3, Pacetti and Alt are applied to the claim as stated above.

Regarding claim 4, Pacetti and Alt are applied to the claim as stated above.

Response to Arguments

8. Applicant's arguments filed 2 September 2010 have been fully considered but they are not persuasive. Applicants have stated that the invention was made prior to the

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cited prior art, but there is no evidence on record to support these statements. The rejections based on the Alt reference are in effect.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER KESSLER whose telephone number is (571)272-6510. The examiner can normally be reached on Mon-Fri, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Roy King/
Supervisory Patent Examiner, Art
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csk

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